

VERSION WITH MARKINGS TO SHOW CHANGES MADE



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TC 3700 MAIL ROOM

IN THE SPECIFICATION:

1. Please amend the paragraph beginning at page 42, line 35 as follows:

As shown in Fig. 34, the distal portion of shaft 702 is introduced anteriorly through a small percutaneous penetration into the annulus fibrosus 710 of the target spinal disc. To facilitate this process, the distal end of shaft 702 may taper down to a sharper point (e.g., a needle), which can then be retracted to expose active electrode(s) 704. Alternatively, the electrodes may be formed around the surface of the a tapered distal portion of the shaft (not shown). In either embodiment, the distal end of shaft 702 is delivered through the annulus 710 to the target nucleus ~~pulposus-pulposus~~ 290, which may be herniated, extruded, non-extruded, or simply swollen. As shown in Fig. 35, high frequency voltage is applied between active electrode(s) 704 and return electrode(s) ~~710-706~~ to heat the surrounding collagen to suitable temperatures for contraction (i.e., typically from about 55°C to about 70°C). As discussed above, this procedure may be accomplished with a monopolar configuration, as well. However, applicant has found that the bipolar configuration shown in Figs. 34-36 provides enhanced control of the high frequency current, which reduces the risk of spinal nerve damage.

2. Please amend the paragraph beginning at page 43, line 12 as follows:

As shown in ~~Fig.~~ Figs. 35 and 36, once the nucleus pulposus-pulposus 290 has been ~~sufficient~~ sufficiently contracted to retract from impingement on the ~~nerve~~ nervous tissue 720, the probe 700 is removed from the target site. In the representative embodiment, the high frequency voltage is applied between active and return electrode(s) 704, 706 as the probe is withdrawn through the annulus 710. This voltage is sufficient to cause contraction of the collagen fibers within the annulus 710, which

allows the annulus 710 to contract around the hole formed by probe 700, thereby improving the healing of this hole. Thus, the probe 700 seals its own passage as it is withdrawn from the disc.

IN THE CLAIMS:

Kindly amend the claims as follows:

32. (Amended) A method for treating tissue within a patient's spine comprising:

positioning an electrode in contact with, or in close proximity to, an outer surface of an annulus of a disc within the patient's spine, wherein the annulus has an opening therein; and

applying a high frequency voltage to the electrode, the voltage being sufficient to at least partially close ~~an~~ the opening in the annulus.

35. (Amended) The method of claim 32 ~~wherein~~ further comprising:
prior to the positioning step, percutaneously introducing the electrode is introduced through a percutaneous penetration in to the patient's spine.

38. (Amended) The method of claim 32 further comprising:
positioning a return electrode on the outer surface of the patient's body, and conducting ~~electrical~~ electric current from the electrode, through the patient's body, to the return electrode.

39. (Amended) The method of claim 32 wherein the step of positioning the electrode comprises positioning a single, active electrode in at least close proximity to the outer surface of the annulus ~~at the distal end of a shaft.~~

40. (Amended) The method of claim 32 wherein the step of positioning the electrode comprises positioning a plurality of electrically isolated electrode terminals in at least close proximity to the outer surface of the annulus at the distal end of a shaft.

41. (Amended) The method of claim 32 wherein the opening is on an inner surface of the annulus, and wherein the method comprising positioning step comprises positioning the electrode on the outer surface of the annulus adjacent to the opening.

42. (Amended) The method of claim 32 wherein the opening is on the outer surface of the annulus, and wherein the method comprising positioning step comprises positioning the electrode adjacent to, or in contact with, the opening.

43. (Amended) The method of claim 32 ~~wherein further comprising:~~ prior to the positioning step, anteriorly introducing the electrode is introduced to the patient's spine anteriorly.

44. (Amended) The method of claim 32 ~~further comprising wherein the electrode is disposed on an instrument shaft and a return electrode, wherein the electrode and the return electrode are located on the instrument shaft, and wherein the applying voltage step is carried out by~~ comprises applying a the high frequency voltage difference between the electrode and the a second return electrode, the return electrode disposed on the instrument shaft.

45. (Amended) The method of claim 32 wherein the applying voltage step ~~is carried out by~~ comprises applying the high frequency voltage in the range of from about 45 volts rms to 60 volts rms to the electrode.

46. (Amended) The method of claim 32 wherein the applying ~~voltage~~ step is carried out at a voltage level and for a time period sufficient to heat at least a portion of the annulus to a temperature in the range of from about 55° C to 70° CCelsius.

47. (Amended) A method for treating tissue within a patient's spine comprising:

positioning an electrode in close proximity to, or in contact with, an outer surface of an annulus of a an intervertebral disc; and

heating a portion of the annulus to a temperature in the range of from about 55° C to 70° CCelsius.



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Claims 32-47 are pending in this application. Claims 32, 35, and 38-47 have been amended. New claims 48-59 have been added.

1. Rejection under 35 USC 112, 1st paragraph

The Examiner rejected claims 32-47 under 35 USC § 112, first paragraph.

The Examiner stated that the specification did not provide enablement for closing an opening or merely heating the disc while the electrode is in contact with, or in close proximity to, the outer surface of the disc.

Applicant does not concur. Page 43, lines 14-19 of the specification describe applying a high frequency voltage between the active electrode and return electrode as the probe is withdrawn through the annulus, the voltage being sufficient to cause contraction of the collagen fibers within the annulus, which allows the annulus to contract around the hole formed by the probe, such that the probe seals its own passage as it is withdrawn from the disc.

Thus, closing the opening or hole in the annulus is disclosed as being due to contraction of collagen fibers in the annulus.

Page 6, lines 14-20 of the specification describes heating collagen fibers, either by directing a jet or plume of heated electrically conducting fluid towards the target tissue, or by passing electric current through the tissue. (It is well known in the art of electrosurgery that electric current flows into tissue adjacent to an active electrode and causes resistive heating of the tissue (see, e.g., page 11, lines 16-21 of the specification)). Thus, a target tissue can be heated by applying a voltage to an electrode, without the electrode being in contact with the target tissue, either by passing electric current through the tissue, or by directing a jet of heated fluid towards the tissue.

Therefore, collagen-containing tissue can be heated, and collagen fibers can be contracted, by an electrode in close proximity to, or in contact with, the tissue.

As the electrode is withdrawn from the disc (see, e.g., page 43, lines 14-19 of the specification), the electrode may make *contact with* the outer surface of the disc, as it leaves the annulus fibrosus; and subsequently, the electrode is *in close proximity to* the *outer surface* of the annulus as the electrode is moved away from the disc.

Thus, applicant submits that claims 32-47 are fully enabled by the specification as filed. Accordingly, applicant respectfully requests that the Examiner's rejection of claims 32-47 under 35 USC 112, first paragraph, be withdrawn.

2. Rejection under 35 USC 112, 2nd paragraph

Claims 32-46 were rejected under 35 USC § 112, second paragraph as being indefinite.

The Examiner rejected claim 32 as being indefinite for failing to positively recite that the disc includes an opening.

Applicant does not concur. However, in an attempt to expedite prosecution of the instant application, claim 32 has been amended to recite the annulus as having an opening therein.

The Examiner stated that claim 35 was set forth in passive voice, as opposed to active voice.

In an attempt to expedite prosecution, claim 35 has been amended to recite percutaneous introduction of the electrode as an additional method step.

The Examiner stated that claims 39 and 40 recite structure without additional methodology.

In an attempt to expedite prosecution, claims 39 and 40 have been amended to recite the claim limitations as method steps.

The Examiner stated that claim 43 was set forth in passive voice, as opposed to active voice.

In an attempt to expedite prosecution, claim 43 has been amended to recite introduction of the electrode as an additional method step.

Regarding claim 44, the Examiner correctly pointed out that “the second electrode” lacked antecedent basis.

Claim 44 has been amended to delete “the second electrode.” Therefore, claim 44 is no longer indefinite.

Accordingly, applicant respectfully requests that the Examiner’s rejection of claims 32-46 under 35 USC 112, second paragraph, be withdrawn.

3. Rejection under 35 USC 102 (e)

Claim 47 was rejected under 35 USC § 102 (e) as being unpatentable over Sharkey, *et al.* (U.S. Patent No. 6,007,570).

Applicant’s claim 47 recites the step of positioning an electrode in close proximity to or in contact with an *outer surface* of an annulus of a disc.

Sharkey *et al.* does not disclose positioning an electrode in close proximity to or in contact with an *outer surface* of an annulus of a disc. On the contrary, the ‘570 describes guiding the intradiscal section of the catheter to selected sections on or adjacent to the *inner wall* of the annulus fibrosus (see, for example, col. 10, lines 63-67, and Fig. 4 of the ‘570).

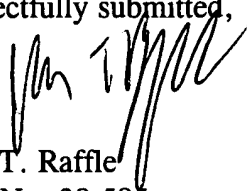
Accordingly, applicant submits that claim 47 patentably distinguishes over Sharkey *et al.*

Furthermore, Applicant submits that claim 47 defines an invention which is unobvious over Sharkey *et al.* Sharkey *et al.* does not suggest the method steps recited in claim 47.

Accordingly, it is submitted that the claims are in condition for allowance. Reconsideration of the rejections is respectfully requested. Allowance of the claims at an early date is solicited.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at (408) 736-0224.

Respectfully submitted,



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